

# Development of a Cleft Facial Aesthetic outcome measure for children born with a complete Unilateral Cleft Lip and Palate

**Principle Applicant:** Bruce Richard

## **Scientific outline:**

**Proposed investigation:** The current method to assess facial aesthetic outcome of cleft surgery is to use the 'Asher McDade' system where human raters score a cropped photograph on a scale of one to five. This is used internationally but is subjective with poor reliability. We want to understand why it is so subjective, use improved methodology to achieve a score that is both valid and reliable. We then want to convert the scoring method from human assessors to automated computer image analysis. We want the outcome measure to be relevant for cleft professionals and the cleft community.

There are three main work streams:

1. Improve Photo scoring methodology. To score the Clinical Standards Advisory Group (CSAG 1998) and Cleft Collective UK (CCUK 2012) 2-Dimensional A/P photo sets. To score only the lip by Human raters using a Likert scale of 1-5 and Symnose<sup>®</sup>. Symnose is a computer software package that measures asymmetry of an upper lip.
2. Create an automated facial aesthetic outcome measure from the 2-D photo negatives. The automated image analysis would involve creating a computer software program that can measure the image and score it the same as Symnose and humans would, but more reliably and objectively.
3. Discover Patient and Parent opinion on Photo scoring by using the same photo scoring system but by parents and patients.

**Clinical Benefits:** Development of an outcome measure for facial appearance after infant cleft lip and palate repair would allow audit of outcomes for surgeons and centres, comparison of protocols, surgical techniques, and surgeons.

## **Study Design**

All three studies will be based on two data sets of 5 year old cleft patient facial A/P and profile photographs. This data is securely held by the Bristol Cleft Collective (NIHR) and was originally collected as research data for the CSAG and CCUK studies. We have a long established relationship with Professor's Ness and Sandy and their team in Bristol.

**Ethics:** There is on-going Ethical permission to use this data for subsequent studies as long as the patient held data remains anonymised. Separate ethical approval. Will be sought for the following 2 issues:

1. To allow patients and parents to score anonymised cropped central third of face photos we are in discussion with the Chief Executive of the Cleft Lip and Palate Association of UK (CLAPA), and with the West Midlands Patient Voices Group.
2. The Computer subtraction imaging technology to extract just the lip from the surrounding skin is not possible on compressed low resolution JPEG type files and needs the original camera negative file. We will need to access the original image files from each cleft centre, securely sent to the Bristol Collective, re-anonymise and crop them and then release them to our group.

Therefore, ethical approval will be sought in our IRAS and REC application, to ensure the clinical governance confidence to be able to publish our results.

#### **Research Management**

These research studies will be based will at the Birmingham Children's Hospital, UK.